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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,798	09/12/2003	H. Paul Redmond	1194-282	6154

6449 7590 04/11/2007

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/11/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/660,798	REDMOND ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,7,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 1/11/2007, have been fully considered and are persuasive in part. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 1-3, 6-7 and 9-10 are currently pending and are the subject of this Office Action. Claims 4-5, 8 and 11 are cancelled.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-3, 6-7 and 9-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Carter in view of WO 92/00743.

The reasons were given previously; the traverse is unpersuasive. Applicants have amended claims 1 and 10 to recite the methylol transfer agents taurolidine and taurultam.

Briefly, Carter discloses that 5-fluorouracil (5-FU) is useful to treat the instantly recited cancers (see especially page 78). The reference differs from the instant claims in that it does not disclose a combination therapy comprising 5-FU and taurolidine or taurultam to treat cancer.

However, WO 92/00743 discloses a method of treating cancer with taurolidine and taurultam (pages 1-3). The reference also contemplates co-administering taurolidine and/or taurultam with "other agents known to be involved in tumor metabolism" or "cytotoxic agents" (page 3, first paragraph).

Claims 1-3, 6-7 and 9-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Carter in view of U.S. Patent No. 6,303,596.

The reasons were given previously; the traverse is unpersuasive.

Carter discloses that 5-FU is useful to treat the instantly recited cancers (see especially page 78). The reference differs from the instant claims in that it does not disclose a combination therapy comprising 5-FU and taurolidine or taurultam to treat cancer.

However, the '596 patent discloses a method of treating cancer with taurolidine and taurultam (abstract, claims).

It would have been *prima facie* obvious to combine 5-fluorouracil and taurolidine or taurultam to treat cancer. Taurolidine and 5-FU are individually known in the art as agents for treating cancers, whose efficacy when administered alone is well established for the treatment of

a large number of neoplasias and metastasis. It is generally obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven*, 205 U.S.P.Q. 1069 (CCPA 1980). The idea for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett*, 126 U.S.P.Q. 186, 188 (CCPA 1960). Accordingly, to establish obviousness in such fact situations it is NOT necessary that the motivation come explicitly from the reference itself (although Examiner believes it does, as discussed *supra*). The natural presumption that two individually known anticancer agents would, when combined, provide a third composition also useful for treating cancer flows logically from each having been individually taught in the prior art. Applicant has presented no evidence (*e.g.* unexpected results) to rebut this natural presumption.

Response to Arguments

Applicants state, "...the present specification describes an unexpected synergistic effect of the combination of 5-FU and a methylol transfer agent in the treatment of cancer." While it is true the specification states that such a synergistic effect occurs, there is no evidence in the specification to support this assertion. In support of the unobviousness of the claimed invention, Applicants provide a Declaration from Dr. Paul Redmond (submitted 1/11/2007). In said Declaration, Dr. Redmond states that his studies have demonstrated that taurolidine in combination with 5-FU is more effective than 5-FU alone. Data is presented demonstrating the synergistic effect of taurolidine and 5-FU on the proliferation of SW 480 colo-rectal tumor cells.

The Declaration of Dr. Redmond and data therein are persuasive only for the treatment of colo-rectal tumors with the combination of taurolidine and 5-FU. However, the claims are much broader in scope than the evidence of unexpected results provided in the Declaration. For example, claim 1 recites the inhibition of any tumor growth with a combination of 5-FU and "taurolidine, taurultam or a mixture thereof". It is not evident from the data presented that such a synergistic effect will be observed in all tumors, or even in colo-rectal tumors when 5-FU is combined with taurultam. As noted in the previous Office Actions, 5-FU and taurolidine were both known in the art as effective treatments for cancer. Further, WO 92/00743 suggests combining taurolidine and/or taurultam with "other agents known to be involved in tumor metabolism" or "cytotoxic agents" (page 3, first paragraph).

As such, the rejection of claims 1-3, 6-7 and 9-10 as being obvious over Carter in view of WO 92/00743 and Carter in view of 6,303,596 are maintained for the reasons of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent No. 6,479,481

Claims 1-3, 7 and 9-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 5-6 of U.S. Patent No. 6,479,481. Although the conflicting claims are not identical, they are not patentably distinct from each other because '481 discloses a method of treating tumors of the central nervous system using the methylol transfer agents taurolidine, taurultam or a mixture thereof and that said methods may further comprise a "cytotoxic antineoplastic agent".

Applicants appear to acquiesce, as the responses filed 5/15/2006 and 1/11/2007 did not traverse this rejection but did indicate that applicants would be willing to file a Terminal Disclaimer "should any conflicting claims be found allowable." As no such claims have been found allowable, the rejection is maintained.

Allowable Subject Matter

Favorable consideration would be given to claims limited to the inhibition of colo-rectal tumor growth comprising administering a combination of 5-FU and taurolidine.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

March 29, 2007

PHYLLIS SPIVACK
PRIMARY EXAMINER

Phyllis Spivack
3/28/07